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John K. Fitzgerald, Reg. No. 38,881

COFC
Certificate
JUN 30 2005
of Correction



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of

TIMOTHY R. MACHOLD ET AL.

Patent No.: 6,890,347 B2

Issued: May 10, 2005

Serial No: 10/628,055

Filed: July 25, 2003

For: DISPOSABLE CASSETTE FOR
INTRAVASCULAR HEAT
EXCHANGE CATHETER

Examiner: Robert L. Nasser

Group Art Unit: 3736

Client ID/Matter No: RADME 64499

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since these errors occurred in both the final printing phase of the patent and in the final application, a check in the amount of \$100.00 is enclosed to

06/28/2005 HVUONG1 00000028 6890347

01 FC:1811

100.00 OP

JUL - 5 2005

cover the necessary fees. Should the Office determine that additional fees are needed, please charge Deposit Account No. 06-2425.

The errors are verifiable in the patent application file as follows:

ERROR

VERIFICATION

Column 1, line 26, delete "99.6" and insert --98.6--.

Patent Application filed on July 25, 2003.
See Attachment A, page 1.

Column 4, line 64, delete "printing" and insert --priming--.

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See Attachment A, page 6.

Column 5, line 57, delete "though" and insert --through--.

Applicant error.

Column 11, line 27, delete "illustrates" and insert --illustrated--.

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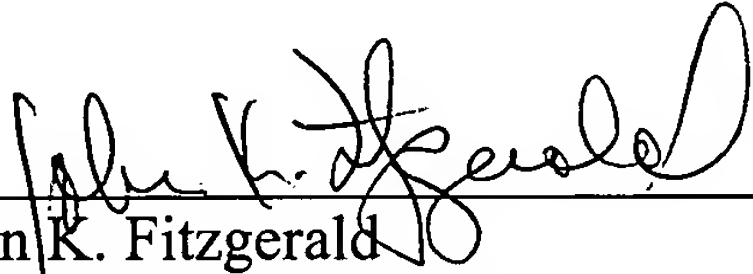
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Date: June 23, 2005

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:



John K. Fitzgerald
Registration No. 38,881

JKF:ck
Enclosures

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201

93629.1

DISPOSABLE CASSETTE FOR INTRAVASCULAR HEAT EXCHANGE CATHETERIntroductionCross Reference To Related Applications

5 This application is a Continuation-In-Part of U.S. Patent Application Serial No. 09/138,830, filed on August 24, 1998; and claims the benefit of US Provisional Application No. 60/185,561, filed on February 28, 2000.

Technical Field

10 The present invention is directed to a fluid supply and fluid handling mechanism for an intravascular heat exchanger, and more particularly to a disposable cassette with a pump head and an external heat exchanger for use as a system to provide hot or cold heat transfer fluid to an intravascular heat exchange catheter.

Background

15 Under ordinary circumstances, thermoregulatory mechanisms exist in the healthy human body to maintain the body at a constant temperature of about 37°C (98.6°F), a condition sometimes referred to as normothermia. To maintain normothermia, the thermoregulatory mechanisms act so that heat lost to the environment is replaced by the same amount of heat generated by metabolic activity in the body.

20 For various reasons, however, a person may accidentally develop a body temperature that is above or below normal, conditions known as hyperthermia or hypothermia respectively. These conditions have generally been regarded as harmful and patients suffering from either condition have been treated to return them to normothermia by various mechanisms, including application of warming or cooling blankets, administration of hot or cold liquids by mouth, hot or cold liquids infused into the bloodstream, immersion of the patient in hot or cold baths, and
25 directly heating or cooling blood during cardiopulmonary bypass.

Besides treating undesirable hypothermia to reverse the condition and restore normothermia, medical science recognizes that it is sometimes valuable to intentionally induce and maintain regional or whole body hypothermia for therapeutic reasons. The term "whole body hypothermia" refers to the condition where the whole body temperature, usually measured
30 as the core body temperature, is below normothermia. "Regional hypothermia" refers to the condition where target tissue of one region of the body such as the brain or the heart is maintained at a temperature below normothermia. During regional hypothermia, the core body

Another aspect of the invention is a disposable cassette for supplying a heat exchange fluid to an intravascular heat exchange catheter, the cassette having a bulkhead and an external heat exchanger. The external heat exchanger has a thin heat exchanger layer and a back plate fused together to form a serpentine flow channel or a plurality of flow channels, and has an inlet orifice and an outlet orifice that allow fluid to circulate through the external heat exchanger and which communicate with the bulkhead. In one embodiment, the bulkhead has three components which can be independent sections coupled together or where at least two of the sections are housed together: a reservoir section, a feedblock section and a pump section. The reservoir section has an inlet hole leading from the external heat exchanger and an outlet leading to the feedblock section, a fluid reservoir for storage of heat exchange fluid, a fluid level detector for monitoring the level of heat exchange fluid within the fluid reservoir, a cover plate that functions to retain fluid within the reservoir and which is fitted with at least one vent hole into which is positioned a hydrophobic vent for releasing air contained within the fluid reservoir. The feedblock section has a central chamber which houses a priming valve that directs fluid flow, an inlet and corresponding inlet channel from the reservoir and an inlet and corresponding inlet channel from an external fluid source which both lead into the central chamber, an outflow channel leading from the central chamber to an outlet which is directed to the pump head, a flexible membrane covering the central chamber, a flow-through channel having an inlet which leads from the pump head and a fluid coupling outlet means for fluidly connecting the catheter to the bulkhead, and a flow-through channel having a fluid coupling inlet means for fluidly connecting the catheter to the bulkhead and an outlet which leads to the pump section and then to the external heat exchanger. The pump section has a quasi-cardioid shaped cavity, into which is positioned a rotor is fitted with a vane for moving fluid from an inlet and inlet channel to an outlet channel and outlet, a wheel assembly to facilitate movement of the rotor and a flow-through channel having an inlet that leads from the feedblock section and an outlet which leads to the external heat exchanger.

In yet another aspect of the invention, the bulkhead has two components: a reservoir section and a pump section, where the pump and reservoir sections are configured similar to that described above, except that the outlet of the reservoir section leads to the pump section and the reservoir further comprises a pressure damper and an inlet in fluid communication with an external fluid source.

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,890,347 B2

DATED : May 10, 2005

INVENTOR(S) : Timothy R. Machold et al.

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MAILING ADDRESS OF SENDER:

**John K. Fitzgerald
Fulwider Patton Lee & Utecht LLP
6060 Center Drive, 10th Floor
Los Angeles, CA 90045**

PATENT NO. 6,890,347 B2

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Page 1 of 1

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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/628,055
Filing Date	7/25/03
First Named Inventor	Machold et al.
Art Unit	3736
Examiner Name	Robert L. Nasser
Attorney Docket Number	RADME-64499

ENCLOSURES (Check all that apply)

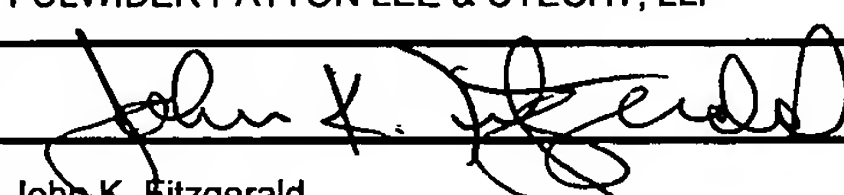
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<input type="checkbox"/> Certified Copy of Priority Document(s)
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)
<input type="checkbox"/> Licensing-related Papers

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<input type="checkbox"/> CD, Number of CD(s) _____
<input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
Request for Certificate of Correction (+Exhibit A), Certificate of Correction, Postcard |
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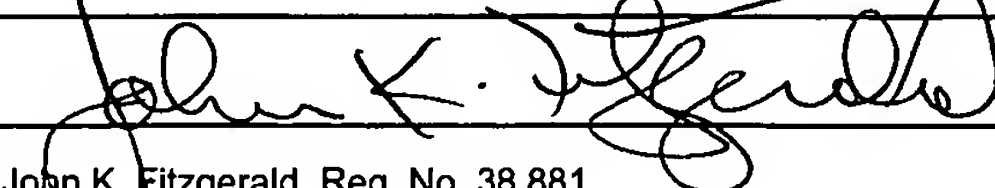
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	FULWIDER PATTON LEE & UTECHT, LLP		
Signature			
Printed name	John K. Fitzgerald		
Date	6/23/05	Reg. No.	38,881

CERTIFICATE OF TRANSMISSION/MAILING

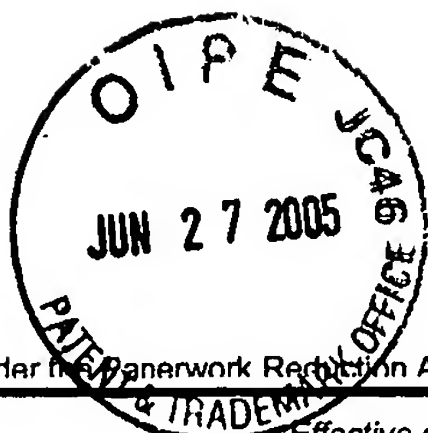
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	John K. Fitzgerald, Reg. No. 38,881	Date	6/23/05

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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**FEE TRANSMITTAL**
For FY 2005☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 100.00

Complete if Known

Application Number	10/628,055
Filing Date	7/25/03
First Named Inventor	Machold et al.
Examiner Name	Robert L. Nasser
Art Unit	3736
Attorney Docket No.	RADME-64499

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____
☒ Deposit Account Deposit Account Number: 06-2425 Deposit Account Name: FULWIDER PATTON

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☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	0

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

Fee (\$)	Small Entity Fee (\$)
50	25
200	100
360	180

Each independent claim over 3 (including Reissues)

Multiple dependent claims

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP =	x	=	0

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 3 or HP =	x	=	0

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee (\$)	Fee Paid (\$)
	0

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x	=	0

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Request for Certificate of Correction

Fees Paid (\$)

\$100.00

SUBMITTED BY

Signature

Registration No. 38,881
(Attorney/Agent)

Telephone 310/824-5555

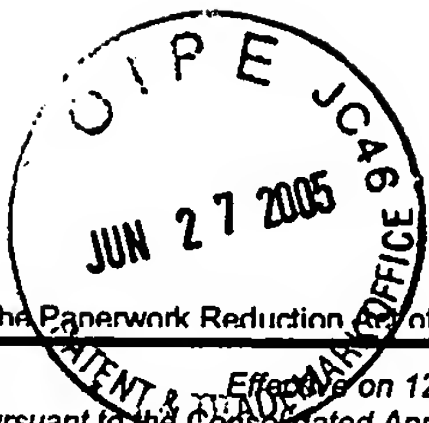
Name (Print/Type) John K. Fitzgerald

Date 6/23/05

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\$100.00

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Signature		Registration No. 38,881 (Attorney/Agent)	Telephone 310/824-5555
Name (Print/Type)	John K. Fitzgerald		Date 6/23/05

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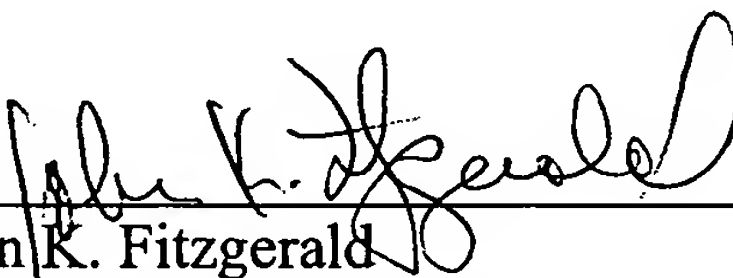
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Respectfully submitted,

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DISPOSABLE CASSETTE FOR INTRAVASCULAR HEAT EXCHANGE CATHETERIntroductionCross Reference To Related Applications

5 This application is a Continuation-In-Part of U.S. Patent Application Serial No. 09/138,830, filed on August 24, 1998; and claims the benefit of US Provisional Application No. 60/185,561, filed on February 28, 2000.

Technical Field

10 The present invention is directed to a fluid supply and fluid handling mechanism for an intravascular heat exchanger, and more particularly to a disposable cassette with a pump head and an external heat exchanger for use as a system to provide hot or cold heat transfer fluid to an intravascular heat exchange catheter.

Background

15 Under ordinary circumstances, thermoregulatory mechanisms exist in the healthy human body to maintain the body at a constant temperature of about 37°C (98.6°F), a condition sometimes referred to as normothermia. To maintain normothermia, the thermoregulatory mechanisms act so that heat lost to the environment is replaced by the same amount of heat generated by metabolic activity in the body.

20 For various reasons, however, a person may accidentally develop a body temperature that is above or below normal, conditions known as hyperthermia or hypothermia respectively. These conditions have generally been regarded as harmful and patients suffering from either condition have been treated to return them to normothermia by various mechanisms, including application of warming or cooling blankets, administration of hot or cold liquids by mouth, hot or cold liquids infused into the bloodstream, immersion of the patient in hot or cold baths, and
25 directly heating or cooling blood during cardiopulmonary bypass.

Besides treating undesirable hypothermia to reverse the condition and restore normothermia, medical science recognizes that it is sometimes valuable to intentionally induce and maintain regional or whole body hypothermia for therapeutic reasons. The term "whole body hypothermia" refers to the condition where the whole body temperature, usually measured
30 as the core body temperature, is below normothermia. "Regional hypothermia" refers to the condition where target tissue of one region of the body such as the brain or the heart is maintained at a temperature below normothermia. During regional hypothermia, the core body

Another aspect of the invention is a disposable cassette for supplying a heat exchange fluid to an intravascular heat exchange catheter, the cassette having a bulkhead and an external heat exchanger. The external heat exchanger has a thin heat exchanger layer and a back plate fused together to form a serpentine flow channel or a plurality of flow channels, and has an inlet orifice and an outlet orifice that allow fluid to circulate through the external heat exchanger and which communicate with the bulkhead. In one embodiment, the bulkhead has three components which can be independent sections coupled together or where at least two of the sections are housed together: a reservoir section, a feedblock section and a pump section. The reservoir section has an inlet hole leading from the external heat exchanger and an outlet leading to the feedblock section, a fluid reservoir for storage of heat exchange fluid, a fluid level detector for monitoring the level of heat exchange fluid within the fluid reservoir, a cover plate that functions to retain fluid within the reservoir and which is fitted with at least one vent hole into which is positioned a hydrophobic vent for releasing air contained within the fluid reservoir. The feedblock section has a central chamber which houses a priming valve that directs fluid flow, an inlet and corresponding inlet channel from the reservoir and an inlet and corresponding inlet channel from an external fluid source which both lead into the central chamber, an outflow channel leading from the central chamber to an outlet which is directed to the pump head, a flexible membrane covering the central chamber, a flow-through channel having an inlet which leads from the pump head and a fluid coupling outlet means for fluidly connecting the catheter to the bulkhead, and a flow-through channel having a fluid coupling inlet means for fluidly connecting the catheter to the bulkhead and an outlet which leads to the pump section and then to the external heat exchanger. The pump section has a quasi-cardioid shaped cavity, into which is positioned a rotor is fitted with a vane for moving fluid from an inlet and inlet channel to an outlet channel and outlet, a wheel assembly to facilitate movement of the rotor and a flow-through channel having an inlet that leads from the feedblock section and an outlet which leads to the external heat exchanger.

In yet another aspect of the invention, the bulkhead has two components: a reservoir section and a pump section, where the pump and reservoir sections are configured similar to that described above, except that the outlet of the reservoir section leads to the pump section and the reservoir further comprises a pressure damper and an inlet in fluid communication with an external fluid source.